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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
FOLEY, SHANON A

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 11/05/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/844,311	HUANG, YUNG T.	
	Examiner	Art Unit	
	Shanon Foley	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 19-51* is/are pending in the application.

4a) Of the above claim(s) *19-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *19-51* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *14* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

In paper no. 16, applicant amended claim 1, cancelled claims 15-18 and added new claims 19-51. Claims 1-14 and 19-51 are pending.

Election/Restrictions

Newly submitted claims 19-51 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Claims 19-47 are drawn to a method of detecting one or more enteroviruses in a sample. MPEP § 806.05(h) states that inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP)). In the instant case the process of using the product can be practiced with materially different product, i.e. BGMK-hDAF cells, a cell line established from a transgenic cell line designated BGMK-hDAF, a transgenic buffalo green monkey kidney cell line expressing human decay accelerating factor or CV-1-hDAF cells. In addition, the product claimed can be used in a materially different process, such as in a method of producing one or more enteroviruses.

Claims 48-51 are drawn to a method for producing one or more enteroviruses. These claims are also independent and distinct from the originally presented claims because enteroviruses can be produced in other cell lines, such as human kidney cells, HeLa, Vero cells, or CV-1-hDAF cells.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution

on the merits. Applicant invokes *In re Ochiai* and *In re Brouwer* on page 12 of the response and states that claims 19-51 are in condition for allowance because the product claims are allowable. However, the products have not been found in condition for allowance for reasons discussed below. Accordingly, claims 19-51 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Claims 1-14 are under consideration.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4 and 6-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scholl et al. (US 6,168,915) and Powell et al. (Journal of General Virology. 1998; 79: 1707-1713) for reasons of record.

Applicant argues that there is no motivation to combine the references. Applicant specifically argues that the teachings of Powell et al. are limited to the expression of DAF in mouse cells. Applicant argues that there is no teaching or suggestion that expressing DAF in buffalo green monkey (BGM) cells would have the same effect observed in the mouse cells of Powell et al. Applicant further argues that Powell et al. teaches away from the instant invention because Powell et al. teach expressing DAF in other cell lines, but that the expression did not confer enterovirus permissiveness. Applicant further asserts that Powell et al. teach away from

the expressing DAF because the reference discloses that enterovirus infection is mediated via unidentified receptors, other than DAF.

Applicant's arguments have been fully considered, but are found unpersuasive. It is well established in the enterovirus art that BGM cells are susceptible to enterovirus infection, see the teachings of Scholl et al. Due to the inherent susceptibility of these cells to enterovirus infection, these cells necessarily contain elements which are required by most enteroviruses for infection. It is also well established in the art that DAF is a cellular receptor used by several enteroviruses for virus attachment and entry, as discussed by Powell et al. Powell et al. express the established DAF enterovirus receptor in WOP cells, which are not susceptible to enteroviruses. Upon expression of DAF, these cells became susceptible to haemagglutinizing enterovirus strains. In other words, Powell et al. clearly demonstrate that these cells had increased susceptibility to enterovirus infection upon expression of the DAF receptor. While Powell et al. increase the susceptibility in mouse cells, increased permissiveness to enterovirus infection in a cell expressing a recombinant DAF receptor would only increase susceptibility in a cell that is already susceptible to enterovirus infection, i.e. buffalo green monkey cells. This is due to the established fact in the art that Buffalo green monkey cells are already susceptible to enterovirus infection. In summary, the art establishes that buffalo green monkey cells are permissive to enterovirus infection. It has also been established in the art that the DAF receptor is required for some forms of enterovirus infection. Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to express the DAF receptor required by some enteroviruses for cell entry in a cell already susceptible to enterovirus infection to expand enterovirus infection to enteroviruses that require the receptor for entry and infection. The

combined teachings of Scholl et al. and Powell et al. teach all of the limitations required by the claims and provide reasons for the ordinary artisan to combine the selected elements in the manner claimed.

Applicant further argues that a reasonable expectation for producing the claimed invention has not been established. Applicant specifically argues that Powell et al. teaches failure to increase permissiveness to all cells expressing DAF. Applicant also argues unexpected results and points to excerpts in the disclosure. The data indicate that H292 cells expressing DAF did not increase sensitivity to viral infection. Applicant also discusses unpredictability of increasing permissiveness by expressing recombinant receptors. References submitted in the IDS which show that expression of HIV CD4 in some cell lines is insufficient to permit virus entry, but that expression in other cell types increased sensitivity.

Applicant's arguments have been fully considered, but are found unpersuasive. The unpredictability with respect to HIV and using recombinant receptors has been reviewed. However, the art cited by applicant is not analogous to the instant invention. HIV and enteroviruses have different modes of replication, infection, etiology and pathology. In addition, the object of the instant invention is drawn to increasing the permissiveness of a cell known to be sensitive to enterovirus infection by expressing a specific recombinant receptor known to be used by enteroviruses. However, the articles supplied by applicant discuss HIV infection in cells that are not normally susceptible to HIV infection, i.e. brain and skin cells, taught by Chesebro et al., extra factors required for HIV entry, taught by Harrington et al. While these references would be relevant to the HIV propagation art, they are not relevant to the enterovirus art.

Contrary to applicant's assertions, Powell et al. do not teach failure to increase the susceptibility in all cells expressing DAF because the reference clearly demonstrates success in WOP cells, which was discussed by applicant in the previous section.

The data regarding the unexpected results showing that expression of DAF in H292 cells did not increase susceptibility to enteroviruses, while expression of DAF in BGM cells does increase permissiveness to enterovirus infection has been considered. However, these results are not clearly unexpected due to the fact that it is established in the art that human tissue culture cells, i.e. H292, are not as susceptible to enterovirus infection compared with buffalo green monkey cells. Melnick (Enteroviruses: Polioviruses, Coxsackieviruses, Echoviruses, and Newer Enteroviduses. *In* B.N. Fields et al. (ed.), Fields Virology, 3rd ed. Philadelphia: Lippencott-Raven Publishers; 1996: 660-661) clearly shows that human cell lines are not as susceptible to enterovirus infection compared to monkey kidney cell culture, see Table 2. Melnick further teaches that buffalo green monkey cells are even more sensitive to enterovirus infection monkey kidney cell lines, see the second full paragraph on page 661. Therefore, due to the fact that buffalo green monkey cells are more sensitive to enterovirus infection that any other cell type and that DAF is a required receptor for some enterovirus types, one of ordinary skill in the art at the time the invention was made would have had a reasonable expectation for increasing the sensitivity of a cell already highly susceptible to enterovirus infection by expressing a receptor known to be required by some enteroviruses for entry and infection.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Scholl et al. and Powell et al. as applied to claims 1-4 and 6-14 above, and further in view of Spiller et al. (Journal of Infectious Diseases. 2000; 181: 340-343) with the sequence alignment of SEQ ID NO: 1 with

GenEmbl database accession no. M15799 of Medoff et al. (PNAS. 1987; 84 (7): 2007-2011), or in the alternative, Spiller et al. with the sequence alignment of SEQ ID NO: 3 with GenEmbl database accession no. M30142 of Caras et al. (Nature. 1987; 325 (6104): 545-549) for reasons of record.

Applicant argues that the sequence alignment of Spiller et al. do not remedy the deficiencies of Powell et al. and Scholl et al. However, as discussed above, there is no deficiency to remedy. Therefore, the rejection is maintained for reasons of record.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley

JAMES HOUSEL 11/3/03
SUPERVISORY PATENT EXAMINER
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